NATIONAL ASIAN WOMEN'S
HEALTH ORGANIZATION

TESTIMONY TO THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997 PUBLIC MEETINGS

MARY CHUNG, PRESIDENT/CEO
National Asian Women's Health Organization
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Thank you for this opportunity to provide commentary to the 1997 FDA Modernization Act. My name is Mary Chung, and I am the president and founder of the National Asian Women's Health Organization.

The National Asian Women's Health Organization, known as NAWHO, is a non-profit, community-based advocacy organization that has significantly changed the health and well-being of Asian American families since its founding in 1993. NAWHO's mission is to improve the health status of Asian women and families through research, education, leadership and public policy programs that empower women, and address broader social justice issues for under-served communities of the entire American population. With offices in San Francisco and Washington, DC, NAWHO represents over 3,000 individual and 150 organizational members from 25 states.

It is evident that the FDA has been a tremendous force in protecting and promoting the health of the American public. The FDAMA confirms many of the innovative new practices of the FDA, while at the same time poses many challenges, especially in maintaining the integrity of consumer protection in light of streamlining operations. On behalf of NAWHO and our constituents, I would like to address broadly such a challenge in one of the FDAMA's objective areas: information clarity on new products. This area is of particular importance to Asian Americans, as well as the women from all different racial backgrounds who are impacted by NAWHO's work in health advocacy.

250 MONTGOMERY STREET
SUITE 410
SAN FRANCISCO
CALIFORNIA 94104

PHONE 415.989.9747
FAX 415.989.9758

E-MAIL NAWHO@NAWHO.ORG

Clear and accessible information for consumers is of the utmost priority. While all of us with an interest in public health push for innovation in disease prevention and treatment, it is imperative that consumer education and knowledge is able to keep up with these new developments. To facilitate this, the FDA and Asian American community advocates must work together to protect the consumer, and strengthen information dissemination regarding new products, unapproved uses, proper dosage, as well as clinical trial results of FDA-approved products.

This is critical for Asian Americans, a population that is two-thirds immigrant, who face tremendous barriers to health care and health care knowledge. For too long, the specific health needs of Asian Americans have been under-estimated, due to stereotypes such as the "model minority" myth, which perpetuates the impression that all Asians are prosperous, educated, and healthy. This stereotype simply is not true for the vast numbers of Asians in the United States, and has limited the implementation of public health intervention and education programs targeted to this population.

The lack of understanding about the health needs of this community is complicated by the fact that Asian Americans living in the United States come from a variety of ethnic backgrounds, and have varying levels of English proficiency, cultural integration, and economic status. For example, approximately 14% of Asian Americans lived in poverty, but when broken down by ethnic group, the rates range from 65% of Hmong living in poverty to less than 10% for Japanese Americans. Southeast Asians in general have the highest welfare dependency rates of any ethnic or racial group. 30% of Asian American households lack an English-proficient speaker over the age of fourteen.

It is this diversity that challenges public health professionals and community health advocates in ensuring that Asian Americans have true access to drug, biologic, and device information, particularly cutting-edge innovations. In this regard, NAWHO urges the FDA to utilize and collaborate with Asian community-based organizations to disseminate information to this multi-lingual and multi-cultural population.

This information should be formulated around the following concerns that we have for our constituency regarding the FDAMA.

With the new allowance of marketing by the manufacturer for unapproved uses of drugs, biologics, and devices, it is critical that the FDA take the steps to ensure that consumers will be educated about such products that have not gone through aggressive scrutiny for its new promoted use. This resonates for minority communities who have suffered from the lack of true informed consent about health care products and services. As the marketing of off-label uses will most likely increase, limited-English speaking Asian Americans become vulnerable to a lack of information that the safety and effectiveness of such products have not been proven in well-controlled clinical trials.

This need for detailed and explicit information has been well-documented in NAWHO studies. In our work on reproductive health, we have urged health care agencies to integrate patient education into their programs, such as information about all the available FDA-approved contraceptive methods, especially with regard to what works to prevent pregnancy, the effectiveness of available methods, and specific short and long term side effects of different methods. While Asian American women are fairly knowledgeable about certain types of contraceptive methods, they are not well informed about others and may have misconceptions about methods they feel comfortable with. For example, some women we have surveyed incorrectly believed that the rhythm method and birth control pills provided some protection against STIs. This lack of information about products remain major reasons for why the health status of many Asian Americans is poor.

To educate the Asian American consumer about off-label use, new products, proper dosage and other FDA related issues requires a well-rounded effort and a multitude of partnerships. NAWHO urges the FDA to develop partnerships with Asian community groups to disseminate information out to different sectors of the community, including consumers, health care professionals, and businesses. For example, organizations such as NAWHO can provide cultural competency training to health care professionals to facilitate the communication of medical information from health care professionals to Asian patients.

Also, the FDA can engage in partnerships with other health care professionals groups on providing information to their patients when prescribing off-label products or to direct them to a source for information. As it does with mammography, the FDA can also provided translated educational brochures about what off-label use of products means, what are the purposes of clinical trials in product approval, and why proper dosage is important. Another information venue could be an information hot-line in different Asian languages that provides recorded information about current off-label uses for the most common drug treatments. Another is to engage with Asian ethnic media to provide a health information or science column to their readers about new products. Finally, the expansion of the well-detailed FDA web site into a multi-lingual capacity would further ease the flow of information to limited-English speaking Asian Americans.

As processes are streamlined, and timelines shortened, public information and education becomes a greater responsibility for the FDA. This again, becomes increasingly complicated as the American public changes in its diversity and ethnic make-up. However, through increased partnerships to increase information dissemination, the FDA will be able to on this ever-expanding role and provide true health access for Asian Americans and other special populations.